SENATE BILL REPORT
ESB 5935

As Passed Senate, March 10, 2015

Title: An act relating to biological products.

Brief Description: Concerning biological products.

Sponsors: Senators Parlette and Frockt.

Brief History:
Committee Activity: Health Care: 2/17/15, 2/19/15 [DP].
Passed Senate: 3/10/15, 48-1.

SENATE COMMITTEE ON HEALTH CARE

Majority Report: Do pass.
Signed by Senators Becker, Chair; Dammeier, Vice Chair; Frockt, Ranking Minority Member; Angel, Bailey, Brown, Cleveland, Conway, Jayapal, Keiser, Parlette and Rivers.

Staff: Kathleen Buchli (786-7488)

Background: A biological product, as defined by federal rule, means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product applicable to the prevention, treatment, or cure of a disease or condition of human beings. These are more complex that traditional chemically synthesized drugs. Biological products are manufactured from living organisms by programming cell lines to produce desired therapeutic substances. Examples of biological products include human growth hormone, injectable treatments for arthritis and psoriasis, the Hepatitis B vaccine, and stem cell therapy.

A biosimilar is a biological product that is highly similar to a biological product, with minor differences in clinically inactive components. A biosimilar is considered to be interchangeable with a biological product if it is determined by the Food and Drug Administration that it can be expected to produce the same clinical result as the reference product in any given patient and there is no risk in terms of safety or diminished efficacy of alternating or switching between the biosimilar and the biological product.

The Affordable Care Act amended the Public Health Services Act to create an abbreviated licensure pathway for biosimilar products that are interchangeable with a Food and Drug

---

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not a part of the legislation nor does it constitute a statement of legislative intent.

Administration-licensed biological product. This is similar to the pathway permitted for drug manufactures to substitute generic drugs for brand-name prescription drugs that have been approved under the Food, Drug, and Cosmetic Act. Under this pathway, the Secretary of Health and Human Services may determine a biosimilar to be interchangeable with a biological product if it is determined that the biosimilar is expected to produce the same clinical result as the reference product in any given patient or there is not likely to be a risk to safety or efficacy by switching to the biosimilar. If the biosimilar is interchangeable, a pharmacy may substitute without the intervention of the health care provider.

Summary of Engrossed Bill: Every drug prescription form must contain an instruction of whether or not a generic drug or an interchangeable biological product may be substituted. If dispense as written is indicated, an interchangeable biological product may not be substituted. Until August 1, 2020, if substitution is permitted, the pharmacist must substitute an interchangeable biological product for the biological product prescribed if the wholesale price of the interchangeable product is less than the wholesale price of the biological product prescribed.

The pharmacist must notify the patient if an interchangeable biological product is being substituted for the drug prescribed. Notification must occur at the time of dispensing. Until August 1, 2020, the pharmacist must also notify the prescriber if an interchangeable biological product is being substituted for the drug prescribed. Notice to the practitioner must be made within five days of the substitution and can be accomplished through use of an electronic medical record if the practitioner has access to the record. If electronic medical records are not available, notification may then be made through other methods including facsimile or telephone. Notification is not required for refills or in situations where the pharmacist has communicated with the practitioner before substitution.

The Pharmacy Quality Assurance Commission must maintain a list of interchangeable biological products on its website.

Pharmacists and pharmacies are provided with protection from liability based on the decision to dispense the interchangeable biological product.

Pharmacies must post a sign that interchangeable biological products may be substituted for the drug prescribed by a patient's doctor.

Appropriation: None.

Fiscal Note: Not requested.

Committee/Commission/Task Force Created: No.

Effective Date: Ninety days after adjournment of session in which bill is passed.

Staff Summary of Public Testimony: PRO: This bill is a starting point and the more controversial points have been left out. We opposed adding notification provisions; generic drug substitution does not require notification and we do not have to add this requirement to interchangeable biologics. Adding in a notice provision will increase costs. Notification is

clinically unnecessary. The federal definition provides that interchangeable drugs may be substituted without notice to the prescriber. Notice will lead to more confusion and may result in people not prescribing biosimilars. Electronic notice may be reasonable. We need to not put limits on the use of interchangeable drugs because they increase access to therapies. They need to be available as quickly and as broadly as possible. The interchangeable drugs are likely to be cheaper than the reference product; we need to be able to use them without barriers that would affect their use. We support the bill without a notification requirement. This is an appropriate approach; no notice is appropriate and requiring notice would have a chilling effect on the use of interchangeables.

OTHER: Two applications for biosimilar products are pending before the Food and Drug Administration. Now is the time to act so we can be ready for these drugs when they are approved. This bill has been the result of significant stakeholder involvement with the prime sponsor. A solution needs to be reached this session. We are concerned with the communication piece. These are drugs that can have serious side effects and doctors need to know what product has been provided to the patient. Notification is not burdensome; doctors need to be aware so they can monitor for adverse effects or interactions. Notification can be accomplished by communicating the substitution to the prescriber within a reasonable time, but no more than ten days after substitution. We have no issues with patient notification and when electronic health records are more widely used, this will be automatic. We suggest that a new line be added to the prescriber's prescription pad that a prescriber could check to request to be notified of substitution of the interchangeable biological product.

Persons Testifying: PRO: Senator Parlette, prime sponsor; Jim Hedrick, Mindy Baker, Dale Fisher, Walgreens; Lis Houchen, National Assn. of Chain Drug Stores; Jeff Rochon, WA State Pharmacy Assn.; Sydney Zvara, Assn. of WA Healthcare Plans; Len Sorrin, Premera Blue Cross; Chris Bandoli, Regence BlueShield; Carrie Tellefson, CVS Health, Regence Blue Shield; Dave Mastin, Mylan Generic Medicine Company.

OTHER: Vicki Christophersen, WA Biotechnology and Biomedical Assn.; Roman Daniels-Brown, Novartis; Trent House, Genentech; Johanna Lindsay, Arthritis Foundation, Great West Region; Susie Tracy, WA State Medical Assn.; Dave Mastin, Mylan Generic Medicine Company; Alyssa Long, citizen.